

REMARKS

Claims 8, 9, 14-16, 19, and 26-29 are currently pending. Claim 8 is currently amended, claim 20-25 are canceled, and claims 28-29 are new.

Support for the amendments to claim 8 can at least be found: i) the paragraph spanning page 7 and 8 (for 70% identity); and ii) in the first sentence under the Summary of Invention section of page 2 of the specification as originally filed, which states “We have discovered that transcription factors G1073 and homologs (G1073 transcription factors) are useful for imparting enhanced resistance and/or tolerance to water deficit in transgenic plants.”

Support for the new claims 28 and 29 can at least be found can in the final sentence of the first full paragraph of page 4 of the specification as originally filed, which states “Crop plants of interest in the present invention include, but are not limited to soy, cotton, canola, maize, wheat, sunflower, sorghum, alfalfa, barley, millet, rice, tobacco, fruit and vegetable crops, and turfgrass”.

Status of the Application

The Office Action of February 4, 2010 stated that the Paul Chomet Declaration filed on May 23, 2010 to address then outstanding rejections under 35 USC §112, First Paragraph failed to explain the meaning of certain terms used in Table 1, did not indicate what promoter A, B, C, D, and E in Table 1 were, and contained black bars in Table 1 that were unclear as to their meaning or use to obscure information. Applicants provide herewith a new Declaration from Dr. Chomet that:

- i) explains the meanings of the terms “NEU”, “NA”, and “Screened”;
- ii) indicates what promoters A, B, C, D, and E are; and,
- iii) replaces the black boxes with the pertinent information.

Applicants note that the inclusion of the black boxes in Table 1 was an inadvertent consequence of reproducing the documents for transmission to the Office and regret any inconvenience this may have caused.

Claim Rejections under 35 USC §112, Second Paragraph

The Office rejected claim 8 as indefinite, alleging that the claim as then pending was unclear as to which plant imparts water deficit tolerance. Applicants have amended claim 8 herewith to indicate “the water deficit tolerance trait imparted by the transcription factor” as per the suggestion of the Office, thus obviating this rejection.

Claim Rejections under 35 USC §112, First Paragraph: Written Description

The Office rejected all pending claims other than claim 19 for failure to comply with the written description requirement, alleging that the Applicants do not describe transgenic plants with enhanced tolerance to water deficit which express transcription factors that have at least 50%, 70%, 80%, or 90% identity to SEQ ID NO:1 and do not describe a “common structural feature that describes a common specific function of providing a water deficit tolerance trait”. The Office further alleges that the Applicants only describe transgenic soybean with enhanced tolerance to water deficit that express sequence ID NO:1.

With respect to the description of “common structural features”, Applicants respectfully direct the Examiners attention to Figure 1, which provides a consensus sequence (SEQ ID

NO:11) obtained from an alignment of the G1067 protein (SEQ ID NO:12), the G1073 protein (SEQ ID NO: 1), a part of a homologous rice protein (SEQ ID NO:2), and a homologous cotton protein (SEQ ID NO:3). Of these proteins, SEQ ID NO:1 is shown in the specification to confer water deficit tolerance, the G1067 protein (53.2% identity to SEQ ID NO:1) is shown to provide drought tolerance to *Arabidopsis* plants in WO 2005/030966 (Example 7, beginning on page 80, and page 83, line 24-25) and was later shown to confer water deficit tolerance to transgenic corn (see data for PHE0004847 for PMON96085 in Table 2 of Affidavit provided herewith), and the full length rice protein (about 54.5% identity to SEQ ID NO:1) was later shown to provide water deficit tolerance (see data for PHE0001233 in Affidavit provided herewith). Applicants also note that another soy protein (PHE0003447; 54.1% sequence identity to SEQ ID NO:1) was also later shown to provide water deficit tolerance (see data for PHE0003447 in Affidavit provided herewith). All of these proteins which confer some degree of water deficit tolerance to transgenic plants contain substantial portions of the conserved sequence domains provided by the Applicants in Figure 1 and SEQ ID NO:11. Applicants respectfully note that these functionally efficacious proteins have no more than about 55% sequence identity to SEQ ID NO:1 and claim 8 as currently amended specifies "a transcription factor having at least 70% identity to SEQ ID NO:1".

With respect to the description of transgenic plants, Applicants respectfully note that working examples of both *Arabidopsis* and soybean plants that exhibit drought tolerance are provided in Example 1. Furthermore, Applicants provide constructive reduction to practice in the form of detailed descriptions of proteins encoded by homologous genes that can be used to practice the invention (i.e. the partial rice protein sequence of SEQ ID NO:2, the cotton protein

sequence of SEQ ID NO:3), and a series of promoters that can be used (see paragraph spanning pages 8 and 9 of the specification). The Applicants also provide constructive reduction to practice in corn, a representative monocot transgenic plant, in the specification as a whole and in Example 1 for SEQ ID NO:1. Furthermore, the data in Table 1 of the Affidavit provided herewith demonstrates that the constructive reduction to practice in corn disclosed in the Specification as filed was subsequently found to provide corn plants with enhanced water use efficiency (i.e. water deficit tolerance). The recent *en banc* decision of the Federal Circuit Court of Appeals has recently reaffirmed its position that both actual and constructive reduction to practice can be used by the Applicant to meet the written description requirement:

We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. (*Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 2008-1248 (Fed. Cir. March 22, 2010) at page 13, citing *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67(Fed.Cir.2006).

In summary, the Applicants have provided both “common structural features” as well as both actual and constructive reduction to practice sufficient to meet the written description requirement for the invention as claimed. Applicants therefor respectfully request withdrawal of the rejections of claims under 35 USC §112 for alleged lack of written description.

Claim Rejections under 35 USC §112, First Paragraph: Enablement

The Office rejected all pending claims for failure to comply with the enablement requirement, alleging that the Applicants do not enable monocot plants or transgenic plants with enhanced tolerance to water deficit which express transcription factors that have at least 50%, 70%, 80%, or 90% identity to SEQ ID NO:1 and do not describe a “common structural feature that describes a common specific function of providing a water deficit tolerance trait”. The Office further alleges that the Applicants only teach transgenic soybean with enhanced tolerance to water deficit that express SEQ ID NO:1. The Office further alleged with respect to enablement of “*a first transgenic crop plant*” that “one would need to use a field screening process to identify the water deficit tolerance trait with any predictability” and that the Application did not teach this distinction in a screening process. The Office also alleged that undue trial and error experimentation would be required to practice the invention as claimed with respect to the use of transcription factors with at least 50, 80, or 90% identity to SEQ ID NO:1.

With respect to enablement of screening processes to obtain “*a first transgenic crop plant*”, the Applicants first respectfully request some justification the Office’s assertion that to practice “the instant invention using a monocot plant, such as corn, one would need to use a field screening process to identify the water deficit tolerance trait with any predictability”. Applicants can find no basis for this assertion in the Chomet Declaration filed on May 20, 2008 and respectfully request that the Office specifically point out such basis, especially in view of the Office’s position that certain terms used in that earlier filed Declaration were not explained and that the meaning of the “black bars” in the Declaration was unclear.

The Applicants point to the level of skill in the art as well as the state of art as supporting the position that one of ordinary skill in the art would not have had to engage in undue experimentation to identify or obtain water deficit tolerant maize transformed with a transgene factor as claimed. First, those skilled in the art implicitly understand that any disclosed transgene-conferred trait, be it herbicide tolerance, insect resistance, or water deficit tolerance, will typically require screening of several independent transgenic plant lines (i.e. distinct transgene insertion events) to identify those transgenic lines which express the trait. For example, US Patent 5,880,275 (cited in the specification) describes screening plants transformed with a gene encoding an insecticidal protein gene to identify transgenic plants that express an insecticidal level of the protein (see Example 5 of US Patent 5,880,275). This implicit understanding is also acknowledged in the specification, which describes in Example 1 screening of *Arabidopsis* plants for water deficit tolerance. Furthermore, applicable assays for determining drought tolerance were well known to those skilled in the art at the time of filing. For example, Sharp et.al., 1988, Plant Physiol. 87: 50-57 describe experimental conditions for measuring maize growth under various controlled water deficit conditions that could be used to screen for water deficit tolerance. The specification also provides an explicit description in the paragraph spanning pages 3 and 4 of the specification as originally filed of determining water deficit plant conditions in maize. Given that the need to screen transgenic plants for the transgene-conferred traits and that assays for determining water deficit tolerance were well known to those skilled in the art at the time of filing, the enablement of the invention as claimed would not require Applicant disclosure of such information (see MPEP §2164.05, citing *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies*,

Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987);
and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463,
221 USPQ 481, 489 (Fed. Cir. 1984)).

With respect to the scope of enablement with respect to transcription factors with various percent identities to SEQ ID NO:1, Applicants first note that the claims as currently amended specify “a transcription factor having at least 70% identity to SEQ ID NO:1”. Applicants further note that the Affidavit provided herewith provides evidence that SEQ ID NO:1, the full length rice protein containing SEQ ID NO:2 (about 54.5% identity to SEQ ID NO:1), and a another soy protein (PHE0003447; 54.1% sequence identity to SEQ ID NO:1) all provided water deficit tolerant transgenic corn. The Office asserts that “(t)he Declaration implies that..G1067 (SEQ ID NO:12) does not produce said water deficit tolerance in a transgenic corn plant”. Applicants respectfully point out that the data in Table 1 of the previously provided Declaration merely shows that the transgenic G1067 corn plants tested did not exhibit such tolerance at “a construct level” (i.e. across a population of multiple independent transgenic G1067 corn plants for a single G1067 recombinant DNA expression vector). However, the data disclosed in the previously provided Declaration should not be construed as indicating that G1067 cannot produce water deficit tolerant transgenic corn. The Declaration filed herewith provides data in Table 2 indicating that transgenic corn comprising a G1067 recombinant DNA expression vector can exhibit water deficit tolerance (see data for PHE0004847 for PMON96085 in Table 2 of Affidavit provided herewith). It is thus clear that one of ordinary skill in the art would not need to engage in undue experimentation to obtain a transcription factor having at least 70% identity to SEQ ID NO:1, obtain transgenic monocot plants such as corn, wheat, or rice that express the

transcription factor, and then identify individual transgenic plant events that exhibit water deficit tolerance when the Applicants have shown that they could recover such transgenic plants when using genes with less than 55% identity to SEQ ID NO:1 and methods of transformation and screening that are either taught by the specification or routinely employed by those of ordinary skill in the art.

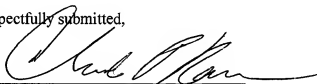
In summary, the Applicants have provided evidence the state of art and disclosure of the application as filed would enable one of ordinary skill in the art to make and use the transgenic plants of the invention as claimed without resorting to undue experimentation. Applicants therefor respectfully request withdrawal of the rejections of claims under 35 USC §112 for alleged lack of enablement.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant, therefore, respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that a personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

It is not believed that any extensions of time or other fees are required beyond those which may otherwise be provided for in documents accompanying this Response. However, in the event that additional extensions of time or fees are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a), and any fees required therefore or for other matters are hereby authorized to be charged to our Deposit Account 20-0823.

Respectfully submitted,



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